

Institutional Animal Care and Use Committee		UNTHSC
Title: IACUC Guidelines for Reporting Serious Noncompliance to OLAW		
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A. BACKGROUND INFORMATION

PHS Policy, IV.F.3, requires that: "The IACUC, through the Institutional Official, shall promptly provide OLAW with a full explanation of the circumstances and actions taken with respect to:

- a. Any serious or continuing noncompliance with this Policy;
- b. Any serious deviation from the provisions of the Guide [for the Care and Use of Laboratory Animals] ; or
- c. Any suspension of an activity by the IACUC."

IACUC suspensions of activities are cited at IV.C.6 and 7 of the Policy, and require a convened meeting of a quorum of the IACUC and the vote of a majority of the quorum present. The Institutional Official must review the reasons for suspension in consultation with the IACUC, take appropriate corrective action and report that action with full explanation to OLAW (Office of Laboratory Animal Welfare).

B. RESPONSIBILITIES

- a. It is the responsibility of all personnel (students, staff, faculty) to report or self-report issues of non-compliance.
- b. It is the responsibility of the IACUC to report instances of serious non-compliance to the IO (Institutional Official). Reports will be made to OLAW.

C. OLAW GUIDANCE ON PROMPT REPORTING

- a. A comprehensive list of definitive examples of reportable situations is impractical. Therefore, the examples below do not cover all instances but demonstrate the threshold at which OLAW expects to receive a report. Institutions should use rational judgment in determining what situations meet the provisions of IV.F.3 and fall within the scope of the examples below, and consult with OLAW if in doubt. OLAW welcomes inquiries and discussion and will provide guidance with regard to specific situations.
- b. Examples of reportable situations:
 - i. Conditions that jeopardize the health or well-being of animals, including natural disasters, accidents, and mechanical failures, resulting in actual harm or death to animals;

- ii. Conduct of animal-related activities without appropriate IACUC review and approval;
 - iii. Failure to adhere to IACUC-approved protocols;
 - iv. Implementation of any significant change to IACUC-approved protocols without prior IACUC approval as required by IV.B.7.;
 - v. Conduct of animal-related activities beyond the expiration date established by the IACUC (note that a complete review under IV.C is required at least once every three years);
 - vi. Conduct of official IACUC business requiring a quorum (full Committee review of an activity in accord with IV.C.2 or suspension in accord with IV.C.6) in the absence of a quorum;
 - vii. Conduct of official IACUC business during a period of time that the Committee is improperly constituted;
 - viii. Failure to correct deficiencies identified during the semiannual evaluation in a timely manner;
 - ix. Chronic failure to provide space for animals in accordance with recommendations of the Guide unless the IACUC has approved a protocol-specific deviation from the Guide based on written scientific justification;
 - x. Participation in animal-related activities by individuals who have not been determined by the IACUC to be appropriately qualified and trained as required by IV.C.1.f.;
 - xi. Failure to monitor animals post-procedurally as necessary to ensure well-being (e.g., during recovery from anesthesia or during recuperation from invasive or debilitating procedures);
 - xii. Failure to maintain appropriate animal-related records (e.g., identification, medical, husbandry);
 - xiii. Failure to ensure death of animals after euthanasia procedures (e.g., failed euthanasia with CO₂);
 - xiv. Failure of animal care and use personnel to carry out veterinary orders (e.g., treatments); or
 - xv. IACUC suspension or other institutional intervention that results in the temporary or permanent interruption of an activity due to noncompliance with the Policy, Animal Welfare Act, the Guide, or the institution's Animal Welfare Assurance.
- c. Any instance of non-compliance will be brought to the attention of the IACUC and the procedures in 031 Reporting and Investigation of Concerns Involving the Care and Use of Animals will be followed.

D. REFERENCES

- a. OLAW website: <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-05-034.html> downloaded August 19, 2014.
- b. SOP 031 031 Reporting and Investigation of Concerns Involving the Care and Use of Animals